4160-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2011-N-0766]

Agency Information Collection Activities; Proposed Collection; Comment Request; Survey of "Health Care Providers' Responses to Medical Device Labeling"

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing an opportunity for public comment on the proposed collection of certain information by the Agency. Under the Paperwork Reduction Act of 1995 (the PRA), Federal Agencies are required to publish notice in the Federal Register concerning each proposed collection of information and to allow 60 days for public comment in response to the notice. This notice solicits comments on this proposed information collection "Health Care Providers' Responses to Medical Device Labeling."

DATES: Submit either electronic or written comments on the collection of information by [INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER].

ADDRESSES: Submit electronic comments on the collection of information to http://www.regulations.gov. Submit written comments on the collection of information to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. All comments should be identified with the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT:

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SUPPLEMENTARY INFORMATION: Under the PRA (44 U.S.C. 3501-3520), Federal Agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. "Collection of information" is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes Agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires Federal Agencies to provide a 60-day notice in the Federal Register concerning each proposed collection of information before submitting the collection to OMB for approval. To comply with this requirement, FDA is publishing notice of the proposed collection of information set forth in this document.

With respect to the following collection of information, FDA invites comments on these topics: (1) Whether the proposed collection of information is necessary for the proper performance of FDA's functions, including whether the information will have practical utility; (2) the accuracy of FDA's estimate of the burden of the proposed collection of information,

including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

Survey of "Health Care Providers' Responses to Medical Device Labeling"--21 CFR Part 801

(OMB Control Number 0910-New)

The purpose of this study is to determine the most effective device labeling format and inform an FDA's regulatory approach on standardized device labeling. Building upon the research methodology and success of the approach FDA used to evaluate drug labeling, we propose to ask health care providers (HCPs) to evaluate the quality of labeling (e.g. instructions for use, directions) for a medical device and to report the degree to which they could follow those instructions, how useful the information is, and how well organized the information is. This work will allow FDA to assess whether HCPs find the format and content of device labeling clear, understandable, useful, and user-friendly. Findings will provide evidence to inform FDA's regulatory approach to standardizing medical device labeling across the United States.

FDA estimates the burden of this collection of information as follows:

Table 1--Estimated Annual Reporting Burden[1]

Respondents	No. of Respondents	No. of Responses per Respondent	Total Annual Responses	Average Burden per Response	Total Hours
Interviews					
Physicians	6	1	6	1	6
Advanced practice nurses (NPs) and registered nurses	9	1	9	1	9
Medical technicians	9	1	9	1	9
Subtotal	24	1	24	1	24

Table 1--Estimated Annual Reporting Burden[1]

Respondents	No. of Respondents	No. of Responses per Respondent	Total Annual Responses	Average Burden per Response	Total Hours
Survey					
Physicians	120	1	120	.5	60
Advanced practice nurses (NPs) and registered nurses	240	1	240	.5	120
Medical technicians	240	1	240	.5	120
Total					324

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

Dated: October 26, 2011.

Leslie Kux,

Acting Assistant Commissioner for Policy.

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